

WE CLAIM:

1. A pharmaceutical composition comprising micronized clarithromycin, wherein the pharmaceutical composition exhibits improved dissolution characteristics relative to a pharmaceutical composition that includes unmicronized clarithromycin.
- 5 2. The pharmaceutical composition of claim 1, wherein the clarithromycin has a particle size less than 50 microns.
3. The pharmaceutical composition of claim 1, wherein the clarithromycin has a particle size less than 35 microns.
4. The pharmaceutical composition of claim 1, wherein the clarithromycin comprises
10 between approximately 100 mg and approximately 1000 mg.
5. The pharmaceutical composition of claim 1, wherein the pharmaceutical formulation comprises an extended release formulation.
6. The pharmaceutical composition of claim 1, further comprising one or more rate controlling polymers.
- 15 7. The pharmaceutical composition of claim 6, wherein the rate controlling polymers comprises one or more of carbohydrate gums, polyuronic acid salts, cellulose ethers, and acrylic acid polymers.
8. The pharmaceutical composition of claim 7, wherein the carbohydrate gums
20 comprise one or more of xanthan gum, tragacanth gum, gum karaya, guar gum, acacia, gellan, and locust bean gum.
9. The pharmaceutical composition of claim 7, wherein the polyuronic acid salts comprise one or more of alkali metal salts of alginic acid and pectic acid.
10. The pharmaceutical composition of claim 7, wherein the cellulose ethers comprise
25 one or more of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and carboxymethyl cellulose.
11. The pharmaceutical composition of claim 7, wherein the acrylic polymers comprise the acrylic polymer available under the brand name carbopol.

12. The pharmaceutical composition of claim 1, further comprising one or more pharmaceutically acceptable excipients.
13. The pharmaceutical composition of claim 12, wherein the pharmaceutically acceptable excipients comprise one or more of gas generating components, swelling agents, lubricants, and fillers.
14. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a once a day formulation.
15. The pharmaceutical composition of claim 1, wherein the dosage form comprises a tablet or a capsule.
16. The pharmaceutical composition of claim 1, wherein the clarithromycin is micronized in air jet mill.
17. The pharmaceutical composition of claim 1, wherein the clarithromycin is co-micronized with one or more pharmaceutical inert carriers.
18. The pharmaceutical composition of claim 17, wherein the pharmaceutically inert carrier comprises one or more cellulose derivatives, silicate derivatives, and clays.
19. The pharmaceutical composition of claim 18, wherein the cellulose derivative comprises one or more of microcrystalline cellulose and carboxymethyl cellulose.
20. The pharmaceutical composition of claim 18, wherein the silicate derivative comprises one or more of magnesium silicate, colloidal silicon dioxide, magnesium trisilicate, and magnesium aluminicum silicate.
21. The pharmaceutical composition of claim 18 wherein clay comprises one or more of veegum and bentonite.
22. The pharmaceutical composition of claim 17, wherein the amount of pharmaceutically inert carrier comprises between approximately 2% and approximately 25% by weight relative to the total weight of the pharmaceutical composition.

23. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition exhibits improved absorption characteristics relative to a pharmaceutical composition that includes unmiconized clarithromycin.
- 5 24. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises an area-under-the-curve (AUC) comparable to the area-under-the-curve (AUC) of a twice-daily immediate release dosage form.
- 10 25. The pharmaceutical composition of claim 1, further comprising one or more of active ingredients, wherein the active ingredients comprise one or more of omeprazole, metronidazole, amoxicillin, rifampicin, lansoprazole, ciprofloxacin, ethambutol, and ritonavir.
26. The pharmaceutical composition of claim 25, wherein the clarithromycin and the one or more active ingredients are combined in a single pharmaceutical composition.
- 15 27. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition further comprises unmiconized clarithromycin.
28. A process for preparing an extended release tablet of clarithromycin, the process comprising:
- micronizing clarithromycin;
- 20 blending the micronized clarithromycin with one or more rate controlling polymers and pharmaceutically acceptable excipients;
- granulating the blend; and
- compressing to form a tablet.
29. The process of claim 28, wherein the clarithromycin is micronized to have a particle size less than 50 microns.
- 25 30. The process of claim 28, wherein the clarithromycin is micronized to have a particle size less than 35 microns.

31. The process of claim 28, wherein the clarithromycin comprises between approximately 100 mg and approximately 1000 mg of the tablet.
32. The process of claim 28, wherein micronizing comprises micronizing the clarithromycin in an air jet mill.
- 5 33. The process of claim 28, wherein micronizing comprises co-micronizing the clarithromycin with one or more pharmaceutical inert carriers.
34. The process of claim 33, wherein the pharmaceutically inert carrier comprises one or more cellulose derivatives, silicate derivatives, and clays.
- 10 35. A method of treating a bacterial infection in a mammal in need of treatment, the method comprising administering a pharmaceutical composition comprising micronized clarithromycin and one or more pharmaceutically acceptable excipients.
- 15 36. The method of claim 35, wherein the clarithromycin comprises at least some clarithromycin that has been micronized to have a particle size less than 50 microns.
37. The method of claim 35, wherein the clarithromycin comprises at least some clarithromycin that has been micronized to have a particle size less than 35 microns.
- 20 38. The method of claim 35, wherein the clarithromycin comprises between approximately 100 mg and approximately 1000 mg of the pharmaceutical composition.
39. The method of claim 35, further comprising administering one or more of omeprazole, metronidazole, amoxicillin, rifampicin, lansoprazole, ciprofloxacin, ethambutol, and ritonavir with the micronized clarithromycin.